510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K033064

B. Analyte:
Mycoplasma pneumonia

C. Type of Test:
Enzyme-Linked Immunosorbent Assay

D. Applicant:
Trinity Biotech USA

E. Proprietary and Established Names:
Trinity Biotech Captia Mycoplasma IgG Enzyme-Linked Immunosorbent Assay (ELISA)

F. Regulatory Information:

1. Regulation section:
   866.3375
2. Classification:
   Class I
3. Product Code:
   LJZ
4. Panel:
   83

G. Intended Use:

1. Intended use(s):
   The Trinity Biotech Captia Mycoplasma IgG Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the semi-quantitative or qualitative determination of IgG antibodies in human serum to *Mycoplasma pneumoniae* for the determination of immunological experience. The Trinity Biotech Mycoplasma IgG ELISA kit may be used to evaluate paired sera for the presence of seroconversions and a significant increase in specific IgG as an aid in the diagnosis of *Mycoplasma pneumoniae* infection in the adult population.
2. Indication(s) for use:
   The Mycoplasma IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for semi-quantitative or qualitative determination of IgG antibodies in human serum to *Mycoplasma pneumoniae* for the determination of immunological experience. The IgG ELISA kit may be used to evaluate paired sera for seroconversions and the presence of a significant increase in specific IgG as an aid in the diagnosis of *Mycoplasma pneumoniae* infection in the adult population.
3. Special condition for use statement(s):
   Not Applicable
4. Special instrument Requirements:

Single or dual wavelength microplate reader with 450 nm filter

H. Device Description:

This is an ELISA kit that contains Mycoplasma (FH strain, grown in PPLO broth, washed, detergent treated, and sonicated) antigen coated microassay plate in a 96 well configuration, serum diluent, cutoff calibrator, a high positive, low positive, and negative control, horseradish-peroxidase conjugate, Chromogen/substrate solution, wash buffer and stop solution.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Mycoplasma IgG ELISA Test Kit
2. Predicate K number(s):
   K971393
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Detect Mycoplasma IgG antibodies in human serum	Detect Mycoplasma IgG antibodies in human serum
Reagents	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)	Tris BSA Serum Diluent Tris Tween Wash Buffer Goat anti-human IgG (Fc)
Technology	ELISA	ELISA
Reagents	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop	Horseradish Peroxidase Conjugate TMB enzyme substrate Sulfuric Acid Stop
Procedure	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min Stop-add 100µl of stop solution Read at 450nm	Serum incubation-20 min Conjugate incubation-20min Substrate incubation-10min Stop-add 100µl of stop solution Read at 450nm
Calculations	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor	1 cutoff calibrator, high, low, and negative controls Multiply cutoff calibrator by correction factor
Differences		
Item	**Device**	**Predicate**
None	None	none

J. Standard/Guidance Document Referenced (if applicable):

Not Applicable

K. Test Principle:

Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials, (i.e., antigens) to adsorb to plastic surfaces such as polystyrene (solid

phase). When antigens bound to the solid phase are brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen-antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing, followed by the addition of Chromogen/Substrate, Tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H2SO4, the contents of the wells turn yellow. The color, which is indicative of the presence of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Not Applicable. This is a change in name of distributor only. Performance characteristics were established in K971393.
    b. *Linearity/assay reportable range:*
    Not Applicable.
    c. *Traceability (controls, calibrators, or method):*
    Not Applicable
    d. *Detection limit:*
    Not Applicable.
    e. *Analytical specificity:*
    Not Applicable
    f. *Assay cut-off:*
    Not Applicable.
2. Comparison studies:
    a. *Method comparison with predicate device:*
    Not Applicable.
    b. *Matrix comparison:*
    Not Applicable
3. Clinical studies:
    a. *Clinical sensitivity:*
    Not Applicable
    b. *Clinical specificity:*
    Not Applicable
    c. *Other clinical supportive data (when a and b are not applicable):*
    Not Applicable
4. Clinical cut-off:
    Not Applicable
5. Expected values/Reference range:
    Not Applicable.

M. Conclusion:

The Trinity Biotech Captia Mycoplasma IgG ELISA is substantially equivalent in performance to the predicate device for the determination of immunological experience to Mycoplasma IgG antibodies.